Exhibit 11

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

DEFENDANTS' INVALIDITY CONTENTIONS

ether (BDDE), divinylsulfone (DVS), 1,2,7,8-diepoxyoctane (DEO) and p-phenylene bis(ethyl)carbodiimide (BCDI), had been used in approved soft tissue fillers for increased stability and durability. Uncrosslinked HA had been commonly used together with the crosslinked HA to reduce the extrusion force and ease the injection. More specifically, wrinkle fillers containing HA-BDDE and uncrosslinked HA had been disclosed, such as Juvederm® Ultra (J24HV) and Juvederm® Ultra Plus (J30HV) (*Lupo)*, which contains HA-BDDE and at least 10% uncrosslinked or free HA (see *Beasley*, Table 1); the two phase filler composition described in Example 2 of *Debacker*, which contains HA-BDDE and 33% uncrosslinked HA; and the composition disclosed in *Reinmuller II.* The crosslinked HA can have a mixture of high- and low-molecular weight HA (see *Lebreton).*

Pain is a barrier to cosmetic treatment. Lidocaine had been included in various filler products to reduce the pain. Dermal fillers, such as Puragen® Plus, Elevess® and Prevelle® Silk, containing lidocaine and HA crosslinked with each of three different crosslinkers, DEO, BCDI and DVS, respectively, had been approved and reported prior to August 2008 (*Kinney, Elevess™ Summary*, and *Prevelle® Announcement*). Puragen® Plus and Prevelle® Silk also contain uncrosslinked HA, i.e., 6% and 2%, respectively. Preclinical and clinical studies had demonstrated that dermal fillers containing crosslinked HA and lidocaine were stable, effective and durable (see, e.g., *Toth* and *Hanke*). Indeed, a heat sterilized injectable gel containing a crosslinked HA and lidocaine was described in a PCT application filed as early as Dec 24, 1992 (*Reinmuller I*, Example 1).

As a medical device to be injected into a human body, an HA filler must be sterile. Heat sterilization or autoclaving had been used to sterilize almost any type of HA preparations before 2008, crosslinked and/or uncrosslinked HA, with or without lidocaine (*Drizen,* 7:19-25; *Piron,* 5: 19-24; *Lebreton*, Examples 3-4; and *Debacker*, page 14, lines 22-24 and Example 2; *Sadozai,* Example 12; and *Reinmuller I*, Example 1). Although crosslinked or uncrosslinked HA

may be subject to degradation during autoclaving, the sterilized HA fillers can remain stable for months or even years (*Drizen,* 7:44-46; *Lowry*, p1244).

The prior art reported that lidocaine stabilized HA. For example, *Sadozai,* a prior art reference disclosed in the priority documents (e.g., U.S. Prov. App. No. 61/085,956 filed Aug. 4, 2008, 2:25 to 3:9), but omitted in the '475 patent, specifically teaches that "crosslinked HA with lidocaine can have good biostability, and can in some cases have a synergistic effect, increasing G' (the storage modulus)" (*Sadozai,* Example 21). This is consistent with the prior art teaching that adding free radical scavenger to an HA hydrogel decreases viscosity loss due to heat and/or storage (*Ji*, paras. [0061]-[0064]); lidocaine is a potent hydroxyl radical scavenger and singlet oxygen quencher (*Das*); and lidocaine was shown to inhibit HA degradation by the mechanism of hydroxyl radical (*Lindvall*). More specifically, dermal fillers containing lidocaine and a mixture of HA-BDDE and at least 10% uncrosslinked HA (such as some Juvederm® products) had been disclosed in multiple prior art references before August 4, 2008 (see, e.g., *Levy*, *Reinmuller II*, *Wortzman*, and *Hunter*).

Accordingly, as of August 4, 2008, the subject matter claimed in the asserted claims of the '475 and '795 patents was well known and obvious to a person of ordinary skill in the art.

Defendants reserve the right to modify these statements and charts by adding additional prior art references to the extent such modification is appropriate in light of any additional information gained through ongoing investigations or through discovery or in light of amendments to Allergan's infringement contentions or other arguments made or positions taken by Allergan. In particular, no claim chart has been provided for Prevelle Silk, Elevess, or Puragen Plus as additional discovery is needed on the composition of those products. Prevelle Silk, Elevess, or Puragen Plus are nevertheless identified as prior art in this document because they are prior art stable, sterile crosslinked hyaluronic acid dermal fillers containing lidocaine.

B. The Asserted Claims of the '475 and '795 Patents are Invalid under 35